UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION
PREVENTION

MEMORANDUM

DATE: April 9, 2013

SUBJECT: Efficacy Review for SP Ultra 8 Disinfectant Cleaner
EPA Reg. No. 9428-T
DP Barcode: D406466

FROM: Emily Mitchell, Chief EM 4-10-13
Product Science Branch
Antimicrobials Division (7510P)

THRU: Mark Perry, Acting Team Leader MSP
Product Science Branch
Antimicrobials Division (7510P)

TO: Monisha Harris, PM 32/David Liem Monisha Harris 4-10-13
Regulatory Management Branch II
Antimicrobials Division (7510P)

APPLICANT: Sun-Pine Corporation
P.O. Box 287
Brandon, MS 39043

FORMULATION FROM LABEL:

Active Ingredient(s)	% by wt.
Sodium Hypochlorite	8.25%
Inert Ingredients	91.75%
Total	100.00%

I BACKGROUND

The product, SP Ultra 8 Disinfectant Cleaner (EPA File Symbol 9428-T), is a new product. The applicant is requesting registration for the product as a deodorizer, disinfectant, and sanitizer for use on hard, non-porous surfaces in homes, households, schools, non-medical institutions, hotels, office buildings, commercial buildings, lockers rooms, restrooms, kitchens, bathrooms, laundry rooms, eating establishments, food processing plants, nurseries, and sick rooms. Studies were conducted at Gibraltar Laboratories Inc., located at 16 Montesano Road, Fairfield, NJ 07004.

This data package identified as D406466 contained two letters from the applicant's representative to EPA (dated October 15, 2012 and December 05, 2012), EPA form 8570-27 (Formulator's Exemption Statement), EPA Form 8570-34 (Certification with Respect to Citation of Data), EPA Form 8570-35 (Data Matrix), EPA form 8570-4 (Confidential Statement of Formula), six studies (MRID nos. 489741-07 through 489741-12), and the proposed label (dated 2/28/2013).

II USE DIRECTIONS

The product is designed for disinfecting and sanitizing hard, non-porous surfaces such as wall, floors, ceilings, tubs, showers, countertops, sinks, tile, glass, stainless steel, and fiberglass. Directions on the proposed label provide the following information regarding use of the product:

To Disinfect: Prewash surfaces and rinse. Mix 1.5 oz. bleach per gallon of water. Spray, rinse, or wipe surface with bleach solution and let stand for 10minutes. Drain and air dry

To Sanitize: Mix 0.33 oz. with 1 gallon of water. Pre-wash with detergent, rinse, cover surface with bleach solution for at least 5 minutes, drain, let air dry

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use on Hard Surfaces (Against a Broad Spectrum of Bacteria): The effectiveness of disinfectants for use on hard surfaces must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray products). Sixty carriers must be tested with each of 3 product samples, representing 3 different product lots at or below the LCL, against *Salmonella enterica* (ATCC 10708) and *Staphylococcus aureus* (ATCC 6538). To support products labeled as "general disinfectants," killing on 59 out of 60 carriers is required to provide effectiveness at the 95% confidence level.

Disinfectants for Use on Hard Surfaces (Against a Broad Spectrum of Bacteria; Additional Bacteria): Effectiveness of disinfectants against specific bacteria other than those named in the AOAC Use-Dilution Method, AOAC Germicidal Spray Products as Disinfectants Method, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Ten carriers must be tested against specific bacteria with each of 2 product samples, representing 2 different product lots. To support products labeled as

"disinfectants" for specific bacteria (other than those bacteria named in the above test methods), killing of the specific bacteria on all carriers is required.

Sanitizer Test (for inanimate, non-food contact surfaces): The effectiveness of sanitizers for non-food contact surfaces must be supported by data that show that the product will substantially reduce the numbers of test bacteria on a treated surface over those on an untreated control surface. The test surface(s) should represent the type(s) of surfaces recommended for treatment on the label, i.e., porous or non-porous. Products that are represented as "one-step sanitizers" should be tested with an appropriate organic soil load, such as 5 percent serum. Tests should be performed with each of 3 product samples at or below the LCL against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (aberrant, ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048 or 15038). The ASTM method states that the inoculum employed should provide a count of at least 7.5×10^5 colony forming units per carrier. Results must show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes.

Disinfectants for Use as Fungicides (Against Pathogenic Fungi, Using a Modified Method): The effectiveness of liquid disinfectants against specific pathogenic fungi must be supported by efficacy data using an appropriate test. The AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray products) may be modified to conform with the appropriate elements in the AOAC Fungicidal Test. The inoculum in the test must be modified to provide a concentration of at least 10^6 conidia per carrier. Ten carriers on each of 2 product samples representing 2 different product lots at or below LCL must be employed in the test. Killing of the specific pathogenic fungi on all carriers is required.

Virucides: The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

IV SYNOPSIS OF SUBMITTED EFFICACY DATA

1. MRID 489741-07, "AOAC Use-Dilution Method", Test Organisms: *Salmonella enterica* (ATCC 10708) and *Staphylococcus aureus* (ATCC 6538), for SP Ultra 8 Disinfectant Cleaner, by Jozef Mastej. Study conducted at Gibraltar Laboratories, Inc., located at 16 Montesano Road, Fairfield, NJ 07004. Study completion date – January 19, 2012. Study No. GR 2935.

This study was conducted against *Salmonella enterica* (ATCC 10708) and Staphylococcus aureus (ATCC 6538). Three lots (Lot Nos. 070811/1, 070811/2 and 070811/3), of the product, SP Ultra 8 Disinfectant Cleaner were tested using Protocol No. 3242. The test substance was prepared by adding 36 milliliters of the test substance to 732 milliliters of sterile 200 ppm AOAC Hard Water. Cultures of the challenge microorganisms were prepared in accordance with the published AOAC Methods. No organic soil load was added to the cultures. The cultures were prepared with a 48 to 54 hour broth (both organisms) at 36±1°C representing transfers originally derived from at least 3 consecutive 24±2 hour transfers in 10 ml Nutrient Broth but not more then 32 total transfers. For the final subculture step, a sufficient number of 25 x 150 mm tubes containing 20 mL of nutrient broth were inoculated and incubated at 36±1°C for 48 to 54 hours. The test cultures were vortexed for 3 to 4 seconds and allowed to stand for approximately 10 minutes prior to use. The upper portion of the cultures was removed, leaving behind any clumps or debris. The removed portion was transferred to a sterile vessel and used for testing. Using a sterile hook, 27 carriers were aseptically transferred into each of the tubes containing the test culture. The carriers were soaked for 15±2 minutes in the respective test system culture broth. Carriers were then transferred and allowed to dry on filter paper in a sterile petri dish at 36±1°C for 40±2 minutes. Each contaminated and dried carrier was placed into a separate 25 x 150 mm test tube containing 10 mL of the disinfectant solution for 10 minutes at 30 second staggered intervals in a 20±1°C water bath. Following incubation, the subcultures were visually examined for the presence or absence of visible growth. Controls included those for purity, organic sterility, carrier sterility, neutralization confirmation, viability and carrier population. Efficacy data was generated at 8.55% and 8.71% of sodium hypochlorite.

2. MRID 489741-08, "AOAC Use-Dilution Method", Test Organism: *Streptococcus pyogenes* (ATCC 19615), for SP Ultra 8 Disinfectant Cleaner, by Jozef Mastej. Study conducted at Gibraltar Laboratories, Inc., located at 16 Montesano Road, Fairfield, NJ 07004. Study completion date – January 19, 2012. Study No. GR 2936.

This study was conducted against *Streptococcus pyogenes* (ATCC 19615). Two lots (Lot Nos. 070811/1 and 070811/2), of the product SP Ultra 8 Disinfectant Cleaner were tested using Protocol No. 3243. Cultures of the challenge microorganisms were prepared in accordance with the published AOAC Methods. No organic soil was added to the culture. The *Streptococcus pyogenes* cultures were prepared with a 48 to 54 hour broth at 36±1°C representing transfers originally derived from at least 3 consecutive 24±2 hour transfers in 10 ml Nutrient Broth but not more then 32 total transfers. For the final subculture step, a sufficient number of 25 x 150 mm tubes containing 20 mL of nutrient broth were inoculated and incubated at 36±1°C for 48 to 54 hours. The test cultures were vortexed for 3 to 4 seconds and allowed to stand for approximately 10 minutes prior to use. The upper portion of the cultures was removed, leaving behind any clumps or debris. The removed portion was transferred to a sterile vessel and used for testing. Using a sterile hook, 27 carriers were aseptically transferred into each of the tubes containing the test culture. The carriers were soaked for 15±2 minutes in the respective test system culture broth. Carriers were then transferred and allowed to dry on filter paper in a sterile petri dish at 36±1°C for 40±2 minutes. Each contaminated and dried carrier was placed into a separate 25 x 150 mm test tube containing 10 mL of the disinfectant solution for 10 minutes at 30 second staggered intervals in a 20±1°C water bath. Following incubation, the subcultures were visually examined for the presence or absence of visible growth. Controls included those for purity, organic sterility, carrier sterility, neutralization confirmation, viability and carrier population. Efficacy data was generated at 8.55% of sodium hypochlorite.

3. MRID 489741-10, "AOAC Fungicidal Activity of Disinfectants", Test Organism: Trichophyton mentagrophytes (ATCC 9533), for SP Ultra 8 Disinfectant Cleaner, by Jozef Mastej. Study conducted at Gibraltar Laboratories, Inc., located at 16 Montesano Road, Fairfield, NJ 07004. Study completion date – January 19, 2012. Study No. GR 2934.

This study was conducted against *Trichophyton mentagrophytes* (ATCC 9533). Two lots (Lot Nos. 070811/1 and 070811/2), of the product, SP Ultra 8 Disinfectant Cleaner were tested using Protocol No. 3241. Six mL of the test substance was added to 122mL of 200 ppm AOAC hard water. No organic soil load was added to the suspension. Five mL of prepared bactericide at the concentration to be tested was pipette into 25 x 150 mm glass test tubes. The tubes were then placed in a 20±1°C water bath for ≥15 minutes before initiation of the test. Each solution was inoculated with 0.5 mL of the conidia suspension. The inoculated tubes were mixed immediately and were returned into the water bath. After 5, 10, and 15 minute intervals, a loopful of the conidia-disinfectant mixture were removed with a sterile 4 mm loop and transferred to 10 mL of primary broth. A loopful of the primary broth was then transferred into 10 mL of the secondary broth. The broth tubes were incubated at 28°C to 32°C for 10 days. Controls included those for purity, organic sterility, carrier sterility, neutralization confirmation, viability and carrier population. Efficacy data was generated at 8.55% sodium hypochlorite.

4. MRID 489741-12, "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces", Virus: Influenza Virus Type A2 Strain A/Hong Kong/8/68 (ATCC VR-544) for for SP Ultra 8 Disinfectant Cleaner, by Chuan Wang, Ph.D. Study conducted at Gibraltar Laboratories, Inc., located at 16 Montesano Road, Fairfield, NJ 07004. Study completion date – July 23, 2012. Study No. GR 2959.

This study was conducted against Influenza Virus Type A2 Strain A/Hong Kong/8/68 (ATCC VR-544) using Madin Darby canine kidney cells (ATCC CCL-34) as the test system. Two lots (Lot Nos. 070811/1 and 070811/2), of the product, SP Ultra 8 Disinfectant Cleaner were tested using Protocol No. 3258. The stock pools were prepared from the supernatant of infected MDCK cell culture. Each stock pool was tittered and stored in an ultra-low temperature freezer. Frozen viral stock was thawed on the day of the test and the organic soil load was adjusted to at least 5% following ASTM E2197-11 9. An aliquot of 0.2 mL of the prepared virus mixture was spread over a marked area of a sterilized glass Petri dish. The virus was allowed to dry completely under the biosafety cabinet at room temperature with the airflow on to facilitate drying. The virus films were dried at 23.0°C at a relative humidity of 26.1% for 10 minutes. Host MDCK cells were plated into 24-well plates and incubated at 37°C, 5% CO_2, and 90% relative humidity on day before test. The disinfectant/challenge virus reaction mixture was scraped off the hard surface and mixed thoroughly right before the completion of contact time. Immediately after the 10 minute contact time, 0.1 mL of disinfectant/virus reaction mixture was taken and the disinfection activity was quenched immediately by diluting with 0.9 mL of EX-Cell MDCK Serum-Free medium/L-glutamine/PS/Trypsin 2.5µg/mL. Then subsequent 10-fold serial dilutions were carried out with diluent immediately to 10^6 and each dilution was inoculated into the prepared host cell plates, 0.1 mL per well and four determinations per dilution. Inoculated plates were incubated at 37°C, 5% CO_2, and 90% relative humidity. Dilutions were then assayed for infectivity and/or cytotoxicity. Controls included those for treatment of dried virus film, cytotoxicity, and assay of non-virucidal level of test substance.

5. MRID 489741-11, "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces", Virus: Human Rhinovirus (HRV) 42, Strain 56822 (ATCC VR-338) for for SP Ultra 8 Disinfectant Cleaner, by Chuan Wang, Ph.D. Study conducted at Gibraltar Laboratories, Inc., located at 16 Montesano Road, Fairfield, NJ 07004. Study completion date – July 23, 2012. Study No. GR 2958.

This study was conducted against Human Rhinovirus (HRV) 42, Strain 56822 (ATCC VR-338). Two lots (Lot Nos. 070811/1 and 070811/2), of the product, SP Ultra 8 Disinfectant Cleaner were tested using Protocol No. 3257. The stock pools were prepared from the supernatant of infected Vero cell culture. Each stock pool was tittered and stored in an ultra-low temperature freezer. Human Rhinovirus cell cultures were maintained in DMEM/5% FBS/PS. The harvested viral stock contained 5% organic soil load. Frozen viral stock was thawed on the day of the test. An aliquot of 0.2 mL of the prepared virus mixture was spread over a marked area of a sterilized glass Petri dish. The virus was allowed to dry completely under the biosafety cabinet at room temperature with the airflow on to facilitate drying. The virus films were dried at 21.9°C at a relative humidity of 30.6% for 8 minutes, 10 seconds. The disinfectant/challenge virus reaction mixture was scraped off the hard surface and mixed thoroughly right before the completion of contact time. Immediately after the 10 minute contact time, 0.1 mL of disinfectant/virus reaction mixture was taken and the disinfection activity was quenched immediately by diluting with 0.9 mL of 100% FBS. Then subsequent 10-fold serial dilutions were carried out with diluent immediately to 10^6 and each dilution was inoculated into the prepared host cell plates, 0.1 mL per well and four determinations per dilution. Inoculated plates were incubated at 33°C, 5% CO_2, and 90% relative humidity. Dilutions were then assayed for infectivity and/or cytotoxicity. Controls included those for treatment of dried virus film, cytotoxicity, and assay of non-virucidal level of test substance.

6. MRID 489741-09, "Efficacy of Sanitizers for Use on Inanimate Non-Food Contact Surfaces", Test Organisms: *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352) for SP Ultra 8 Disinfectant Cleaner, by Jozef Mastej. Study conducted at Gibraltar Laboratories, Inc., located at 16 Montesano Road, Fairfield, NJ 07004. Study completion date – January 17, 2012. Study No. GR 2937.

This study was conducted against *Klebsiella pneumoniae* (ATCC 4352) and *Staphylococcus aureus* (ATCC 6538). Three lots (Lot Nos. 070811/1, 070811/2 and 070811/3), of the product, SP Ultra 8 Disinfectant Cleaner were tested using Protocol No. 3244. One milliliter of the test substance was added to 255 milliliters of sterile 200 ppm AOAC Hard Water. 20µL of the prepared inoculums were spread over the entire area of the sterile glass slides. The inoculated slides were dried for 35 to 40 minutes at 37±1°C and then aseptically transferred into individual, sterile glass jars. Five mL of the test material was added to each jar at 30 second intervals. *Klebsiella pneumoniae* (ATCC 4352) and *Staphylococcus aureus* (ATCC 6538) broth cultures were grown for 48 to 54 hours at 37±1°C. The culture was representing originally derived from at least 3 consecutive 24±2 hour transfers in 10 mL Nutrient broth. The cultures were vortexed, mixed for 3-4 seconds and allowed to stand 10 minutes at room temperature. The upper portion of each culture was removed leaving behind any debris or clumps and was then transferred to a sterile vessel. After appropriate contact time, 20 mL of the neutralizer broth was added to each jar and thoroughly mixed by vigorously rotating the jars on a flat surface, for approximately 50 rotations followed by hand agitation. Aliquots from each jar were transferred to sterile petri dishes. The plates were poured with TSA and incubated at 37±1°C for 48 to 54 hours. CFUs were counted using

a dark field Quebec colony counter. Controls included those for purity, organic sterility, carrier sterility, neutralization confirmation, viability and carrier population. Efficacy data was generated at 8.55% of sodium hypochlorite.

V RESULTS

MRID No.	Organism	No. Exhibiting Growth/ Total No. Tested			Carrier Population
		Lot No. 070811/1	Lot No. 070811/2	Lot No. 070811/3 (aged)	
489741-07	***Salmonella enterica*** **ATCC 10708**	0/60	0/60	0/60	5.5×10^4
489741-07	***Staphylococcus aureus*** **ATCC 6538**	0/60	0/60	0/60	1.2×10^6
489741-08	***Streptococcus Pyogenes*** **ATCC 19615**	0/10	0/10		3.5×10^4

MRID No.	Organism	Contact Time (mins.)						Carrier Population
489741-10	***Trichophyton Mentagrophytes*** **ATCC 9533**	5		10		15		
		1°	2°	1°	2°	1°	2°	
Lot No. 070811/1		0/10	0/10	0/10	0/10	0/10	0/10	5.1×10^6
Lot No. 070811/2		0/10	0/10	0/10	0/10	0/10	0/10	

MRID No.	Organism	Results			Dried Virus Control $TCID_{50}$/0.1 mL
			Lot No. 070811/1	Lot. No. 070811/2	
489741-12	Influenza Virus Type A2 Strain A/Hong Kong /8/68 (ATCC VR-544)	10^{-1} dilutions	Cytotoxicity	Cytotoxicity	$10^{7.0}$
		10^{-2} to 10^{-6} dilutions	Complete inactivation	Complete inactivation	
		$TCID_{50}$/100µL	$<10^{1.50}$	$<10^{1.50}$	
		Log Reduction	≥ 5.5 $\log_{10}$	≥ 5.5 $\log_{10}$	
MRID	Organism	Results			Dried Virus Control $TCID_{50}$/0.1 mL
			Lot No. 070811/1	Lot. No. 070811/2	
489741-11	Human Rhinovirus (HRV) 42 Strain 56822 (ATCC VR-338)	10^{-1} dilutions	Cytotoxicity	Cytotoxicity	$10^{5.8}$
		10^{-2} to 10^{-6} dilutions	Complete inactivation	Complete inactivation	
		$TCID_{50}$/100µL	$<10^{1.50}$	$<10^{1.50}$	
		Log Reduction	≥ 4.3 $\log_{10}$	≥ 4.3 $\log_{10}$	

MRID No.	Organism	Percent Reduction Results/ Geometric Mean			Contact Time
		Lot No. 070811/1	Lot No. 070811/2	Lot No. 070811/3	
489741-09	***Staphylococcus aureus*** **ATCC 6538**	>99.999 $<1.40 \times 10^1$	>99.999 $<1.40 \times 10^1$	>99.999 $<1.40 \times 10^1$	5 mins.
489741-09	***Klebsiella pneumoniae*** **ATCC 4352**	>99.999 $<1.40 \times 10^1$	>99.999 $<1.40 \times 10^1$	>99.999 $<1.40 \times 10^1$	5 mins.

VI CONCLUSIONS

1. The submitted efficacy data support the use of the product, SP Ultra 8 Disinfectant Cleaner, as a disinfectant with bactericidal activity against the following microorganisms on hard, non-porous surfaces without the presence of an organic soil load for a contact time of 10 minutes:

Salmonella enterica (ATCC 10708)	**MRID 489741-07**
Staphylococcus aureus (ATCC 6538)	**MRID 489741-07**
Streptococcus pyogenes (ATCC 19615)	**MRID 489741-08**

Acceptable killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralizer effectiveness showed positive growth of the microorganisms.

2. The submitted efficacy data support the use of the product, SP Ultra 8 Disinfectant Cleaner, as a disinfectant with fungicidal activity against *Trichophyton mentagrophytes* (ATCC 9533) **MRID 489741-10** on hard, non-porous surfaces without the presence of an organic soil load for a contact time of 5 minutes. Acceptable killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralizer effectiveness showed positive growth of the microorganisms.

3. The submitted efficacy data support the use of the product, SP Ultra 8 Disinfectant Cleaner, as a disinfectant with virucidal activity against the following microorganisms on hard, non-porous surfaces in the presence of 5% organic soil load for a contact time of 10 minutes.

Influenza Virus Type A2 (Hong Kong Strain/8/68, ATCC VR-544)	10 minutes	**MRID 489741-12**
Human Rhinovirus (HRV) 42 (Strain 56822, ATCC VR-338)	10 minutes	**MRID 489741-11**

Recoverable virus titers of at least 10^4 were achieved. Cytotoxicity was observed in the 10^{-1} dilutions. Complete inactivation (no growth) was indicated in all higher dilutions tested. At least a 3-log reduction in titer was demonstrated beyond the cytotoxic level.

4. The submitted efficacy data support the use of the product, SP Ultra 8 Disinfectant Cleaner, as a non-food contact surface sanitizer against the following organisms on hard non-porous surfaces without an organic soil load for a contact time of 5 minutes.

Staphylococcus aureus (ATCC 6538)	**MRID 489741-09**
Klebsiella pneumoniae (ATCC 4352)	**MRID 489741-09**

VII RECOMMENDATIONS

1. The proposed label may have the following claim, the product, SP Ultra 8 Disinfectant Cleaner, is an effective disinfectant against the following microorganisms on hard, non-porous surfaces without the presence of an organic soil load for a contact time of 10 minutes:

Salmonella enterica (ATCC 10708)
Staphylococcus aureus (ATCC 6538)
Streptococcus pyogenes (ATCC 19615)

The proposed label may have the following claim, the product, SP Ultra 8 Disinfectant Cleaner, is an effective disinfectant against *Trichophyton mentagrophytes* (ATCC 9533) on hard, non-porous surfaces without the presence of an organic soil load for a contact time of 5 minutes.

The proposed label may have the following claim, the product, SP Ultra 8 Disinfectant Cleaner, is an effective disinfectant against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load for a contact time of 10 minutes:

Influenza Virus Type A2, (Hong Kong Strain/8/68, ATCC VR-544)
Human Rhinovirus (HRV) 42, (Strain 56822, ATCC VR-338)

The proposed label may have the following claim, SP Ultra 8 Disinfectant Cleaner, is an effective non-food contact surface sanitizer against the following microorganisms on hard, non-porous surfaces without an organic soil load for a contact time of 5 minutes:

Staphylococcus aureus (ATCC 6538)
Klebsiella pneumoniae (ATCC 4352)

Data provided support these claims.

2. The following revisions to the proposed label are recommended:

- Specify what type of fiberglass
- On page 3, rewrite directions "Spray, rinse, or wipe surface with bleach solution and let stand for 10 minutes." This statement is confusing to a consumer.